UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,748	02/28/2002	Paul K. Wolber	10020405-1	8764

7590 05/24/2007

AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
05/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,748	WOLBER ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/30/07, 4/17/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-12,15 and 16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-12, and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment to the specification filed 1/30/07 is acknowledged and entered. The amendment to the claims filed 4/17/06 was previously acknowledged and entered.

Claims 1-8, 10-12, and 15-16 are currently pending with claims 1-8, 10-12, and 15 under consideration. Claim 16 has been previously withdrawn in the Office action mailed 1/6/06.

Withdrawn Rejections/Objections

The following rejections and objections set forth in the previous Office action mailed 1/6/06 are hereby withdrawn in view of the amendment to the claims filed 4/17/06 or to the specification filed 1/30/07:

The objection to the specification;

The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter rejection);

The rejection of claim 10 under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

The rejection of claims 1, 7-8, and 15 under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (IDS document: WO 97/10365, 3/20/1997) ;

The rejection of claims 2-3, 5, and 10-12 under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (WO 97/10365, 3/20/1997), as applied to claims 1, 7-8 and 15 above, in

view of Chenchik et al. (US patent no. 6,077,673, Date of Patent: June 20, 2000) and further in view of Lewin, B., (Genes IV, 1990, Oxford University Press);

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (WO 97/10365, 3/20/1997), as applied to claims 1, 7-8, and 15 above, in view of Chenchik et al. (US patent no. 6,077,673, Date of Patent: June 20, 2000) and further in view of Darnell et al. (Molecular Cell Biology, Eds., 1990, published by Scientific American Books); and

The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (WO 97/10365, 3/20/1997), as applied to claims 1, 7-8, and 15 above, in view of Chenchik et al. (US patent no. 6,077,673, Date of Patent: June 20, 2000) and further in view of Feinberg et al. (Analytical Biochemistry, Vol. 132, pages 6-13, 1983).

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 10 recite "calibrating probes that hybridize to a majority of target molecules in sample solutions to which the molecular array is intended to be exposed."

The specification does not provide adequate description for such a limitation. As a matter of fact, the specification repeatedly stress that the calibrating probes hybridize to "large fractions of target molecules first on page 16, then on page 22 and also on page 27. Large fractions is a relative term which could include any fractions that are relatively large, such as 20%, 40%, whereas "a majority" is interpreted as more than 50% ("majority" is defined as "a number or percentage equaling more than half of a total" in Merriam-Webster's Online Dictionary, 10th Edition). The specification does not adequately describe calibrating probes that hybridize to a majority of target molecules. Therefore, one skilled in the relevant art would have reasonable doubt that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-8, 10-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in the "selecting" step recites "each containing calibrating probes that hybridize to a majority of target molecules in sample solutions to which the molecular array is intended to be exposed to produce corresponding signal intensities upon reading of the calibrating probes." The metes and bounds of the claimed invention are not clear because it is not clear what is meant by "corresponding signal intensities." It is unclear as to what corresponds to what. Furthermore, the metes and bounds of the limitation "signal intensities upon reading of the calibrating probes" are also unclear.

Claim 1 recites the molecular array "includes a set of calibrating features, each containing calibrating probes that hybridize to a majority of target molecules in sample solutions ... and a set of features containing probes that hybridize to specific target molecules under stringent conditions." The fact that the claim uses the phrase "specific target molecules" and "under stringent conditions" on to describe the hybridization for the "set of features," but not for the "set of calibrating features" makes it unclear as to whether those two "conditions", i.e. hybridizing to "specific target molecules" and "under stringent conditions," also apply to the calibrating probes. In other words, it is unclear whether the hybridization between the "calibrating probes" and the "majority of target molecules" can be nonspecific and under any stringency of conditions.

Claims 1 and 10 in their respective "selecting" step recite "the total concentration of target molecules in the sample solutions." The singular form "concentration" together with the plural "target molecules" and plural "sample solutions" makes the metes and bounds of the claimed invention unclear. It is not clear whether it means the total concentration of all the different target molecules in all the different sample solutions or the concentration for a particular target molecule in a particular sample solution.

Claim 1 recites "reading the molecular array to determine individual signal intensities for features and calibrating features of the molecular array." The metes and bounds of the limitation are not clear because it is unclear as to what is meant by "individual intensities." The claim recite, prior to this limitation, that the molecular array includes "a set of calibrating features, each containing calibrating probes" and " a set of features." It is thus not clear whether individual intensities means the intensities determined for individual probes of a particular feature, or for individual features of a particular set, or else.

Claim 1 recites in the last step "applying to the signal intensities a normalization function that includes the calculated collective calibration signal." The phrase "the calculated collective

calibration signal" lacks clear antecedent basis because there is no prior reference to a calculated collective calibrating signal, per se, albeit a calculated collective calibrating signal intensity.

Claim 2 recites "[t]he method of claim 1, wherein probes contained in the molecular array are oligonucleotides complementary to cDNA copies of cDNA transcripts of eukaryotic mRNA molecules." The metes and bounds of the claimed invention are not clear because it is not clear whether the phase "probes contained in the molecular array" means all the probes including calibrating probes in the set of calibrating features and those probes in the features that hybridize to specific target molecules, or only means the latter. Furthermore, the metes and bounds of the meaning of the term "cDNA copies" and "cDNA transcripts" are not clear. It is unclear what is meant by "cDNA transcripts" of a mRNA, neither is it clear what is meant by "cDNA copies of cDNA transcripts."

Ditto for claims 3-6, where it is not clear whether the phase "probes contained in the molecular array" means all the probes including calibrating probes in the set of calibrating features and those probes in the features that hybridize to specific target molecules, or only means the latter.

Claims 5 and 6 recite "cDNA copies of the mRNA molecules." It is unclear what is meant by "cDNA copies" of mRNA molecules. It is not clear whether they are the same as "cDNA copies of cDNA transcripts" recited in claims 2 and 4, or "cDNA transcripts of ... mRNA molecules" also recited in claims 2 and 4, or both, or neither.

Claim 7 recites "the set of calibrating signal intensities." The phrase lacks clear antecedent basis because there is prior reference to "a set of calibrating signal intensities," although there is reference to "a set of collective calibrating signal intensities" or "sets of similar calibrating signal intensities."

Claim 7 also recites "the feature of the molecular array." The phrase lacks clear antecedent basis because there are prior references to "a set of calibrating features" and "a set of

features" on the array recited in claim 1, from which claim 7 depends, and it is thus unclear which particular "feature" is meant in claim 7.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D., can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

sz/SZ

SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER